UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS and 01-CV-339	)	
TRIAL OF CLASS 2 AND 3 CLAIMS		

AFFIDAVIT OF JOHN F. AKSCIN
SUBMITTED AS DIRECT TESTIMONY IN CASE-IN-CHIEF
OF DEFENDANTS BMS AND OTN IN TRIAL OF CLASS 2 AND 3 CLAIMS

STATE OF MISSOURI)
) ss:
COUNTY OF ST. LOUIS)

JOHN F. AKSCIN, being duly sworn, deposes and says:

1. I am Vice President, Government Relations, and Customer Champion for Oncology Therapeutics Network, J.V., a Delaware limited partnership ("OTN"). I submit this affidavit based on personal knowledge and files in the possession of OTN as direct testimony in the case-in-chief of defendants Bristol-Myers Squibb Company ("BMS") and Oncology Therapeutics Network Corporation ("OTN Corporation") in the trial of Class 2 and 3 claims in the above-captioned action.

I. Corporate, Business And Personal Background

2. Defendant OTN Corporation was formed in 1990. It is a Delaware corporation, with its headquarters in South San Francisco. In 1993, BMS and OTN Corporation

created OTN as a joint venture, with BMS owning a 21.78% interest and OTN Corporation owning a 78.22% interest. In 1996, BMS acquired OTN Corporation, thereby acquiring the remainder of OTN. From then until 2005, OTN was a wholly-owned subsidiary of BMS. Effective May 11, 2005, OTN became an independent, privately-held company.[1]

3. At all relevant times, OTN has sold drugs, supplies and related services to private office-based oncology providers. Its job is to anticipate and fill the needs of oncologists and their staff in running a safe, effective and profitable cancer-care practice. It is a member of a trade association known as the Specialty & Biotechnology Distributors Association.

4. I joined OTN in December 1999. I graduated from St. Louis University in 1973. In the 25 years prior to joining OTN, I held several jobs relating to the business of practicing medicine. For example, in the late 1970's, I became the director of a diagnostic imaging center (i.e., MRI's, CT scans) for a large hospital in the metropolitan St. Louis area.

5. In 1986, I became the chief administrative officer of an office-based oncology practice called Oncology Care Center in Belleville, Illinois. I held that job until 1999. I was responsible for all non-clinical operations of the Center, including but not limited to ordering drugs and supplies, managing inventory, negotiating contracts with private insurance companies and overseeing all billing of and reimbursement from government payors like Medicare, private payors and individual co-payors. Thus, prior to joining OTN, I had thirteen years of "hands-on" experience in the costs and benefits of running a private office-based oncology practice.

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[1] Today, OTN is a Delaware limited partnership with its corporate office in South San Francisco, California. Defendant OTN Corporation is its general partner. OTN Participant, Inc. ("OTN Participant") is the sole limited partner. Oncology Holdings, Inc., a Delaware corporation owns 100% of the capital stock of OTN Corporation and OTN Participant.

6. My first title at OTN was Director of Business Development. The job consisted of (i) putting OTN customers and potential customers in touch with outside consulting firms (such as medical billers and coders) that helped oncologists set up and run their practices; (ii) evaluating technologies (such as dosage calculators or electronic medical records software); and (iii) communicating with customers, state oncology societies and the OTN sales force via newsletters, e-mails, telephone and formal speaking engagements information and guidance on billing and reimbursement issues affecting office-based oncology practices.

7. In October 2002, my title changed to Director (and later Vice President) of Government Relations to reflect the importance of the third element above of my initial job at OTN. Many cancer patients are beneficiaries of the government's Medicare program. As I will discuss in greater detail, since the mid-1990's there had been a growing debate between and among government stakeholders (the Clinton Administration, HHS and HCFA, Congress, the Department of Justice) and private groups (insurers, providers, state oncology societies and cancer patient advocates) over Medicare Part B's methods for reimbursing oncology drugs and services. OTN's many clients around the country naturally had questions about legislative and regulatory issues related to Medicare and, over time, it became an increasing part of my job at OTN to be a resource for them on those issues.

8. In March 2005, my title changed once again, this time to Vice President of Government Relations and Managed Care Services. The addition of Managed Care Services was a recognition of the influence that not only Medicare, but large private payors like Aetna U.S. Healthcare and United Health Care have in the viability of office-based oncology. My role is to facilitate discussions between office-based oncology practices and the payors focused on quality of care and reimbursement issues of interest to both sides.

II. Overview Of My Testimony

9. I would like to give the Court an overview of my testimony:

(a) First, I will describe in greater detail the range of goods and services OTN has provided to oncologists. As to goods, OTN has been a distributor for a myriad of manufacturers and OTN did not promote *any* single manufacturer's drugs (its former parent's BMS's included) over another's. As a service, OTN offered its customers publicly-available information about AWPs on all products it sold, but it did not promote or "market" the difference or "spread" between OTN's price to the physician and those AWPs. It was a fact of life under the AWP reimbursement system that office-based oncology practices had a need to know what its profit margins were on each drug prescribed to patients in order to accurately manage their business and engage in financial planning. OTN simply provided oncology practices with the data (published AWPs and actual invoice costs) that allowed them to do so. I believe that OTN – and BMS – did not do anything wrongful in providing its customers with this information.

(b) Second, I wish to convey to the Court my personal experience as an oncology practice administrator prior to joining OTN and as an OTN employee who has communicated daily with such administrators (and the doctors they work for) about reimbursement issues generally. In my experience, (i) it was commonplace in government and industry circles that AWP was not a reliable proxy for acquisition costs for drugs (especially for generics), (ii) a medical practice's profits on drugs subsidized what has generally been perceived as inadequate payments for oncology services specifically and the costs associated with shift from hospital out-patient to physician office cancer-care generally and (iii) no changes in the AWP reimbursement system for drugs could be made unless payments for provider services and patient access-to-care issues were also addressed.

III. The OTN Business Model, Goods and Services

10. Irrespective of its status as a subsidiary of BMS, historically OTN has carried and sold nearly all of the drugs and supplies required by its oncology office customers, which total over [10,000] SKUs manufactured by hundreds of pharmaceutical and medical supply manufacturers. OTN has competed with other major specialty distributors, such as Amerisource Bergen Specialty Group, Cardinal Health, Inc., U.S. Oncology, Priority Healthcare and Florida Infusion in serving oncology practices. In order to remain competitive, OTN has had to market the products of each of these manufacturers and could not play "favorites."

11. Attached hereto at Tab A (Defs' Ex. 2609)[2] is PowerPoint presentation that I created in 2002 entitled "This is OTN," which provides a high-level overview of OTN's business. Attached hereto at Tab B (Defs' Ex. 2581) is a catalog from 2001 that gives the Court a fuller picture of the range of products OTN sold.

12. The primary advantage of the former BMS/OTN corporate relationship to an oncology practice/customer of OTN was that OTN could offer its customers as much as a 4% discount off of list price on BMS' products (other than generic products) that was not likely to be found at other specialty distributors. OTN in its own dealings with customers did not otherwise regularly promote BMS products over those of other manufacturers.

13. That is not to say that OTN did not engage in special promotional programs with individual manufacturers (including but not limited to BMS) when the manufacturer retained OTN for specific projects relating to its particular drugs. OTN was very much interested in such engagements and worked hard to achieve the manufacturer's objectives. The last page of the PowerPoint presentation (see Tab A at BMS/AWP/001511824) shows

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2 Each document attached hereto has been cross-referenced to its corresponding exhibit number on the joint-defendants' exhibit list as "Defs' Ex. __."

several of the many manufacturers other than BMS with whom OTN has "partnered." Attached hereto at Tab C (Defs' Ex. 2594) are the minutes of a December 2002 meeting of something called the OTN "Program Implementation Committee." The document shows the then "ongoing programs" with a variety of manufacturers, including APP (American Pharmaceutical Partners), Novartis, Amgen, J&J and BMS, among others. (See also Tabs D-F (Defs' Exs. 2557, 2558, 2600), attached hereto, which are examples of agreements between OTN and other manufacturers, including Amgen, Novartis and APP, regarding these programs.) I was a member of the Committee, although I was not an active participant in the underlying programs.

14. Prior to 2001, OTN purchased products directly from manufacturers, which it stored in a warehouse owned by Livingston International, Inc. and resold to medical providers. (Tab A at BMS/AWP/00151823.) From March 2001 through May, 2006, OTN had a distribution arrangement with a drug wholesaler, McKesson Corporation, in which OTN filled orders out of McKesson's inventory. In June, 2006, OTN purchased a distribution center owned by Cardinal Health, Inc. and located in LaVergne, TN. OTN now fulfills all of its customer orders from its LaVergne location using products that OTN purchases directly from manufacturers.[3]

15. Obviously, OTN has competed with other specialty distributors based on price. However, OTN distinguishes itself from other specialty distributors based on other factors. OTN believes that its superior customer service is a key selling point. (See Tab A at BMS/AWP/001511819.) In particular, we felt that it was important for our salespeople to

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[3] Although it was seamless to the customer, for internal corporate accounting purposes, OTN's sales of BMS products were treated differently from OTN's sales of other manufacturers during the period that BMS owned OTN. OTN did not take title to BMS products, but rather acted as BMS' sales agent and received commissions from BMS in the form of inter-company credits. OTN did take title to other manufacturers' products and thus recorded those sales as its own.

understand the business challenges facing office-based oncology practices. That is why I was asked to make a presentation to our sales force at the 2003 National Sales Meeting that addressed the practical considerations our customers face on a regular basis (See Tab G (Defs' Ex. 2607).) We wanted our salespeople to be able to have intelligent conversations with doctors, nurses, practice managers and billing staff about how OTN could help them run a safe, efficient and profitable business.

16. In addition to providing our customers with salespeople that understand their business model, OTN provided the following services:

Lynx Technology

17. Many of the drugs used by medical oncologists require refrigeration or secure storage because of their toxicites. In addition, it is important for physician office practices to accurately control and account for drug inventory, both in order to satisfy patient needs and because the high dollar value of drug inventory. To help practices meet these needs, OTN has made available to customers a "smart" inventory control machine called the "Lynx Station" that holds and keeps track of a practice's purchased inventory. (A picture of a Lynx machine appears at Tab A at BMS/AWP/001511827.) The Lynx machine also has data communication functionality that allows it to communicate electronically with OTN and to order product automatically when inventories fall below preset levels. This interconnection allows OTN not only to increase its sales, but also to capture the practice's prescribing information. OTN then aggregates this data from its clients to create reports that permit a physician to compare its own data to the prescribing patterns of the other oncology practices on both a national and regional level. (See id. at 828-834.) Finally, the machine can also be interfaced

with a practice's management software in order to populate drug claims data required as a part of a practice's billing process.

Network News & OTN's Website

18. Another of the many services that OTN provides its physician office practice customers is "Network News," a newsletter that contains articles on practice management, safety and FDA actions on drugs of interest to oncologists, as well as product advertisements and reimbursement-related information. Annexed hereto at Tab H (Defs' Ex. 2556) is a copy of the January/February 1997 edition of the Network News that was marked at my deposition (although duplicate pages have been eliminated from this version). As the Court will see, part of the reimbursement information that was of interest to our customers were the AWPs and HCPCS Codes (commonly referred to as "J-Codes") for drugs commonly used in cancer treatment. (See, e.g., Tab H at BMS/AWP/000095604.) OTN also offered its customers free telephone support through a company called DocuMedix to answer questions about the proper HCPCS billing codes to use on a bill for a drug or medical service and/or what the published AWP on a drug might be.

19. As the Internet became more and more a part of business life, OTN placed this reimbursement information on its web site, which was called OTN Online and later, Lynx-2-OTN. The web site allows a customer to view our catalog, to place orders, to see its "purchase history" with OTN and to compare that history with AWPs. Through the website, we also allow customers to access the aggregated Lynx Station data that I referred to in paragraph 17 above.[4]

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[4] For some customers, OTN's "in-house" practice support services such as Lynx, Network News and Lynx2OTN were not enough. OTN sometimes referred physicians who were starting or expanding oncology practices or who were having difficulty navigating the complexities of billing and reimbursement to outside consulting firms. I referred OTN clients and prospective clients primarily to two entities: KR Johnson & Associates and Prostat Resources. The first advised on the day-to-day operational management of an oncology practice; the second advised on wider, strategic issues such as

20. The PowerPoint presentation at Tab A contains some screen shots of reports that could be generated by a customer through the OTN website. (See BMS/AWP/001511836-44.) One of these was called the "AWP/Price" report (id. at 839-40), which allowed the customer to select a reimbursement rate (such as AWP-5%) and compare that figure to the amount the customer had paid OTN for the drug. I do not believe that constitutes "marketing" of spread for the following reasons:

(a) First, the AWP/Price report does nothing other than provide an oncology practice with that which it should already know: the price it paid and the published AWP for a drug. OTN simply created computerized tools that put this known information in a readily-retrievable format. With these tools, OTN's physician office practice customers avoid having to cull through invoices and the entire Red Book to weed out that which the computer does for it.

(b) Second, the report does not promote one drug over another based on spread. It provides information on drugs already purchased by the practice and it applies to all manufacturers' drugs equally.

(c) Third, and most importantly, OTN developed the AWP/Price Report and other reimbursement services because office-based oncology practices needed to know these things in order to function.

21. Some people may seek to characterize OTN's readiness to give its customers information about "spreads" as nefarious, whereas from my perspective as an industry participant it was natural and necessary. As I discuss in the next section of my testimony,

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whether a practice should branch out into joint ventures with hospitals or add new services such diagnostic imaging. OTN's hope was that, through these referrals, an oncology practice might become established or more efficient and the practice would buy more products from OTN. OTN did not receive any compensation from these consultants for the referrals.

Medicare and many private payors had adopted a reimbursement system that required OTN's customers to focus on the price of the drugs they bought relative to the AWPs at which they were reimbursed – if the customer's practice was to remain profitable and keep the doors open. Accordingly, I strongly believe that OTN did not act wrongly in any way in helping its customers identify drug margins.

IV. Medicare's AWP System Dictated The OBO Business Model

22. As I noted in discussing my employment history, I have been personally been involved in the business of running office-based oncology practices since 1986. The physician office practice I worked for consisted of three full-time radiation oncologists, three full-time medical oncologists and a part-time diagnostic radiologist. Services performed included Radiation Therapy, Chemotherapy, minimal Lab procedures, CT scanning and film-based radiography. As with many physician office oncology practices, slightly over 50% of these services were provided to Medicare beneficiaries under the Medicare Part B program.

23. We were early adopters among doctors in a movement during the mid 1980s to early 1990s to treat cancer patients in the physician office setting rather than in the hospital out-patient clinics. This movement was largely driven by TEFRA (Tax Equity and Fiscal Responsibility Act of 1982) and Medicare's interest in moving patient services out of the hospital and into the outpatient and, even more desirable, physician office practice environment. Essentially, this movement was seen as a "win-win" for patients, providers and payors. The patients received more individualized attention, better schedules and a more comfortable environment. Doctors could obtain lab work and have drugs mixed more quickly. Payors found that the same regimen delivered in a private office was much cheaper than in a hospital facility.

24. There was, however, considerable cost and risk in running a private oncology practice. The financial viability of what I called "freestanding cancer treatment centers" depended in part of the adequacy of reimbursement from third-party payors, like Medicare Part B which covered many of the seniors who developed cancer. Attached hereto at Tab I (Defs' Ex. 2555) is a copy of a letter I wrote in 1991 to the then administrator of HCFA regarding, among other things, Medicare's proposed reimbursement for chemotherapy drugs at 85% of AWP.[5] I wrote that "while AWP pricing of drugs as a method of reimbursement has its shortcomings, reducing reimbursement to 85% of AWP is considered too severe." I wrote that AWP has "shortcomings" in acknowledgement of the fact that (as HCFA itself stated in its proposed regulations) the AWPs in industry publications were not representative of actual prices between wholesalers and oncologists. I added that 85% of AWP was "too severe" because it did not allow enough profit for oncologists to make on the drugs to make the freestanding cancer center "viable" and to insure "access to this [kind of] care" for Medicare beneficiaries.

25. Many of presentations that I authored at OTN were based on my experience as an administrator of a freestanding cancer treatment center. Annexed hereto at Tab J is an early presentation, dated February 2000 (shortly after I joined OTN), entitled "The Business of Office Based Oncology." This presentation shows that the typical practice's revenue is "Highly Medicare Driven" since 50% of the patients given chemotherapy are covered by Medicare. (See Tab J (Defs' Ex. 2568) at BMS/AWP/001509905-06.) Drugs represent the

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[5] Although the first page of the letter is dated July 26, 1996, the letter was in fact written on July 26, 1991, as the second page correctly notes. I can also confirm that 1991 is the correct time period because that is when HCFA issued a proposed regulation to reimburse Medicare Part B drugs at 85% of published AWP.

overwhelming part of both the practice's expenses and revenue. (Id. at 905-908.)[6] Accordingly, if an oncology practice was going to achieve the "bottom line" of a typical 12% to 17% return on investment (id. at 909) it was going to have to pay attention to the spreads on drugs.

26. The importance of spreads on drugs under Medicare was driven home for me a few months later in June 2000, when news appeared that HHS and HCFA were considering reimbursing for 50 drugs, including several oncology drugs, based on AWPs based on prices developed through government sources rather than industry publications' AWPs. Attached hereto at Tab L (Defs' Ex. 2570) is an e-mail that I wrote to my colleagues at OTN about the development. In it, I wrote that "a proposed Medicare reimbursement change of this magnitude may have a significant impact on our clients." Id. Not surprisingly, as OTN's Director of Business Development, I received numerous e-mails and telephone calls from concerned OTN customers. Attached hereto at Tabs M-P (Defs' Ex. 2569, 2571-73) are some of my notes memorializing those communications. Basically, they involve my transmitting to our customers up-to-date information about which drugs were potentially going to be affected by the new rules.

27. Ultimately, HHS and HCFA reversed course. In the Summer and Fall of 2000, the office-based oncology community, including the Association of Community Cancer Centers, doctors, practice administrators, patient groups and others mobilized members of Congress – many of whom who had placed AWP into the Medicare statute book in 1997 – to write HHS on why the AWPs in the industry publications and the spreads that they provided over acquisition cost were a necessary part of Medicare reimbursement.

28. I have written and lectured about this episode in various PowerPoint presentations during my time at OTN. (See, e.g., Ex. Q (Defs' Ex. 2575), "Reimbursement in

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[6] I updated this presentation in January 2002 with pie charts that make these points in greater and easier to read detail. (See Tab K (Defs' Ex. 2585) at BMS/AWP/001510381-391.)

Office Based Oncology"/Sales Meeting/July 11, 2000.) It is, I believe, one of the best examples in a long policy debate of why Medicare continued using the AWPs in the publications *knowing* that those AWPs were not indicative of physician acquisition costs. Simply put, spread profits based on those AWPs made the aggregate Medicare payments (i.e., for both drugs and services) sufficient to induce doctors to treat patients in their offices rather than moving patents to the hospital setting which was much more expensive for Medicare. (Id. at BMS/AWP/000096640-42.)

29. My attorneys have obtained some of the letters between members of Congress and HHS through Freedom of Information Act requests. I annex three such letters hereto at Tabs R-T (Defs' Exs. 1087, 1089, 1092) because they go into greater detail than do my PowerPoint presentations of just how explicit Congress was, and why, in choosing the AWPs in the publications.

30. The first is an August 3, 2000 letter from Senator Christopher Bond and (then) Senator John Ashcroft to Secretary Donna Shalala of HHS. (See Tab R (Defs' Ex. 1087).) I excerpt some relevant portions here:

> [I]n the Balanced Budget Act of 1997 (BBA), Congress instructed HHS to base Medicare reimbursement for cancer drugs on 95 percent of the "average wholesale price" or AWP, a term widely understood and indeed defined by HHS manuals to reference amounts reflected in specified publications. Later, Congress pegged reimbursement to drugs in the outpatient setting to the same definition of AWP.[7]
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> We understand HHS' concerns that reimbursement rates for many drugs may exceed the actual acquisition costs. According to our oncologists, this margin pays for wastage, spillage and administrative costs . . . . They [also] tell us that,

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[7] This is a reference to the laws enacted in 1999 for the hospital outpatient prospective payment system or "OPPS", which further demonstrates Congress' very deliberate use of the publications' AWPs and the difference between those AWPs and hospital charges on the one hand and physician acquisition costs on the other in calibrating Medicare expenditures.

> although Medicare makes a payment for chemotherapy administrative services, the payment is only a fraction of what is necessary . . . and they use the payment amounts for drugs to help cover these expenses.

31. Another letter, by Senator Spencer Abraham, is to the same effect. (See Tab S (Defs' Ex. 1089).) He writes, that "Congress laid down very clear legislation regarding these [drug] reimbursements in the Balanced Budget Act of 1997, where it instructed HCFA to base these reimbursement rates at 95% of the average wholesale price (assumed to be an industry-accepted AWP, not one derived by government bureaucrats . . . .) This was done . . . to ensure that cancer care providers would receive adequate reimbursements for the care they provide." (emphasis added).

32. Secretary Shalala's response to Senator Abraham's letter – which was a form response sent in some variation to the scores of Members of Congress who wrote her on this issue – conceded that "Medicare payments for services related to the provision of chemotherapy drugs . . . are inadequate." (See Exhibit T (Defs' Ex. 1092).) She stated that HCFA's goal was to "pay correctly for the drugs, and at the same time make changes, as necessary to ensure that Medicare adequately pays for services related to the provision of the drugs."

33. From that episode, it became clear to me that what I called the "Robin Hood mentality" of Medicare reimbursement (redirecting drug profits to subsidize the services losses) would someday change. (See, e.g., Ex. U (Defs' Ex. 2590) at BMS/AWP/001506820.) That is in fact what happened in the Medicare Modernization Act of 2003. Congress moved away from the AWP system in favor of ASP-based reimbursement for drugs, but simultaneously increased payment for oncologists' services. Congress also created a temporary "demonstration

project" as a way to provide extra compensation to oncologists and thereby incentivize them to provide care for Medicare beneficiaries in the office environment.

34. From my personal experience in dealing with OTN customers, the transition from the former AWP-based reimbursement system has had many challenges. The loss in drug revenue has made it that much more important that the practice collect co-payments from patients. Several physician practices in the Pacific Northwest and the New England regions report that they no longer will see Medicare patients in their office unless the patient has supplemental (MediGap) insurance and are sending others without such insurance to the hospital out-patient clinics. It appears that many private payors have not left the AWP-based system for fear that doctors will drop out of their provider networks.

35. The regulatory and legislative history I observed confirms that it was commonplace in government and industry circles (i) that AWP was not a reliable proxy for acquisition costs for drugs (especially for generics which at times transacted at more than 50% below published AWPs), (ii) that spread profits inherent in the AWP system were used to subsidize inadequate payments for oncology patient care services specifically and the shift from hospital out-patient to physician office cancer-care generally and that (iii) from a practice economics and Medicare policy viewpoint, no changes in the AWP payment system for drugs could be made unless legislative action changing the drug reimbursement model and payments for provider services and patient access-to-care issues were also addressed.

36. I respectfully submit that this history belies any attempt by plaintiffs to characterize all discussions of spread between a provider and a drug distributor or manufacturer on drugs as wrongful. During the period under examination, 1991-2005, spreads on drugs were a

large contributor to the business of office-based oncology. It was an inevitable topic of discussion. I believe that OTN and BMS acted well within industry norms.

John F. Akscin

Sworn to before me this
30 day of October 2006

Notary Public

JENIFER JURIS
Notary Public-Notary Seal
State of Missouri, St Louis County
Commission # 06694709
My Commission Expires Mar 16, 2010